

REMARKS

Claims 1, 3-8, 10-21, 24-32 and 34-37 are pending. Claims 1, 3-6, 14, 17, 32, and 33-37 are under examination and claims 7-8, 10-13, 15, 16, 18-21, and 24-31 have been withdrawn from consideration. In the Office action dated June 21, 2007, claims 34-37 were shown as withdrawn from consideration (on PTOL-326 and page 2, paragraph 2) as being drawn to a non-elected invention. Applicants request that dependent claims 34-37 be reconsidered because they depend from claim 32, which is under consideration. No claims have been allowed.

Amendments to claims 1, 20, 21, 24 and 32 are presented herein. These amendments respond to the issues raised in the Office action and do not add new matter because they are based on the original claims and the disclosure, particularly in the Summary of the Invention at page 4, line 25 to page 7, line 25, and at page 9, line 27 to page 10, line 4.

Claim Rejections under 35 USC § 102

The rejection of claims 1 and 32 under 35 USC § 102(e) based on the disclosure in US patent 6,770,479 (Lee et al.) was maintained because the examiner said that "the claim is drawn to a composition comprising synthetic oligonucleotide – or a substantially complementary sequence or -----". Therefore, the opposite strand of said sequence is substantially complementary sequence of about 40 nucleotides in a composition would hybridize to the target sequence."

Claims 1 and 32 have been amended to clarify the sequences of the synthetic oligonucleotides encompassed by the compositions of claims 1 and 32. The claimed compositions are oligonucleotides in a specified size range (about 25 to about 40 nt) that hybridize specifically to a sequence contained in a *pagA* target sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or a sequence that is complementary to a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or RNA equivalent of a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or RNA equivalent of a sequence that is complementary to a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24. The claims further include that at least one synthetic oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and SEQ ID NO:8.

Lee et al. (US Patent No. 6,770,479) disclose a 1,710 nucleotide sequence (SEQ ID NO:4) that contains a subsequence that corresponds to Applicants' target sequences. Whereas Lee et al. disclosed a large sequence that contains many potential subsequences, Applicants selected specific target sequences contained within the larger sequence or its complementary sequence. Applicants' selected oligonucleotides are identified by size limitations and by hybridizing specifically to target sequences consisting of SEQ ID Nos. 21, 22, 23 or 24, or sequences complementary to a sequence consisting of SEQ ID Nos. 21, 22, 23 or 24, or RNA equivalents of the sequences described in the previous two clauses. Lee et al.'s 1,710 nucleotide sequence does not fall in the size range of the oligonucleotides specified in claims 1 and 32, and therefore does not disclose every element of the claimed compositions. A person of ordinary skill in the field of molecular biology would not consider Lee et al.'s disclosure of the 1,710 nucleotide sequence to be identical to the claimed invention. Because of the differences between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention, Applicants' respectfully submit that Lee et al. does not anticipate the claimed compositions. Therefore, Applicants request entry of the amendments presented herein and seek allowance of claims 1 and 32 as amended which overcome the rejection under 35 USC § 102(e).

Rejections under 35 U.S.C. § 112, first paragraph

The rejection of claims 1 and 32 under 35 U.S.C. § 112, first paragraph was maintained for reasons forth in the previous Office action, based on the use of "substantially complementary" because the Examiner alleged that the claims could include "a substantial number of species which lack significant/sufficient complementarity to SEQ ID NO:21/22/23/24."

Applicants have amended claims 1 and 32 as described above in the section related to § 102(e) rejections, and respectfully request that the Examiner refer to that section for a description of the amended claims. Applicants believe that these amendments also respond to the rejections under § 112, first paragraph.

Applicants maintain that a person of ordinary skill in the art of molecular biology would be able to perform mere routine testing based on the high level of skill of a molecular biologist, the guidance in the specification, and the state of the prior art related to nucleic acid hybridization. That routine testing would

be used to assess the performance of synthetic oligonucleotides for characteristics similar to those described in the specification and working examples. That is, a person of ordinary skill in the art of molecular biology would merely perform what that skilled molecular biologist would regard as routine testing based on known parameters to determine if sequences functioned similarly or identically in conditions that may use different reagents. That molecular biologist of ordinary skill would not consider the routine testing and comparison of synthetic sequences in hybridization assays to be undue experimentation.

Applicants believe that the amended claims 1 and 32 and the above arguments fully respond to the rejections under § 112, first paragraph. Applicants request entry of the amendments and allowance of claims 1 and 32.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 3-6, 14, 17 and 32 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite because claims 1 and 32 recite "substantially complementary."

Applicants have amended claims 1 and 32 as described above in the section related to § 102(e) rejections, and respectfully request that the Examiner refer to that section for a description of amended claims 1 and 32. Applicants believe that these amendments also respond fully to the rejections under § 112, second paragraph. Therefore, Applicants respectfully submit that the rejections under § 112, second paragraph are moot and request allowance of amended claims 1 and 32 and dependent claims 3-6, 14, and 17.

Rejoinder of Withdrawn Claims

Applicants responded with traverse to the restriction requirement mailed March 2, 2006, that divided the claims of the application into five groups. Applicants elected composition claims (original claims 1-6, 14, 17, 32 and 33) drawn to oligonucleotides that hybridize specifically to the *pagA* target sequence.

Applicants believe that the amendments presented herein to claims 1 and 32 place the elected claims in condition for allowance. Applicants, therefore, request allowance of the elected independent composition claims 1 and 32 and all pending claims that depend from them.

Applicants have amended the withdrawn independent method claim to include all the limitations of the independent product claims. More specifically, claim 20 has been amended: (1) in the second providing step to delete reference to the probes specific for a *capB* target sequence in a pXO1 plasmid and to amend the references to probes specific for the *pagA* target sequences using language as in amended claims 1 and 32; (2) in the hybridizing step to delete references to the probes specific for a *capB* target sequence; and (3) in the detecting step to delete reference to the *capB* target sequence. By these amendments, Applicants respectfully submit that the independent method claim complies with the requirements for rejoinder as described in the restriction requirement. Applicants, therefore, request rejoinder of claim 20 and allowance of the independent method claim and all pending claims that depend from it.

Applicants have amended withdrawn dependent claim 21 to insert the references to the *capB* probes and target sequence, using the language of original claim 20, to describe the elements that the method further comprises by this dependent claim. Withdrawn dependent claim 24 has also been amended to make it dependent on amended claim 21 and to use more concise language consistent with the amendments to claim 21.

The Examiner stated in the Office action that a complete reply must include cancelation of nonelected claims or other appropriate action under 37 CFR 1.144, by which the applicant may petition the Director to review the restriction requirement at a time after final action on or allowance of claims to the invention elected, but not later than appeal. Applicants have not canceled claims in this reply and, instead, request reconsideration of all of the pending claims in view of the amendments.

Applicants requested reconsideration of the restriction requirement in the response filed on March 13, 2006. Applicants request consideration of the claims listed as withdrawn from consideration by the examiner as being drawn to a non-elected invention, i.e., claims 7-8, 10-13, 15-16, 18-21, 24-31 and 34-37. As stated above, independent method claim 20 has been amended to include the limitations as in product claims 1 and 32 and, therefore, Applicants request rejoinder of the method claims if allowable subject matter is found in the product claims. Applicants also request rejoinder of the *dependent* claims for both the product claims and the method claims, even if those dependent claims refer to *capB* target sequences or *capB* specific probes, or other sequences. If the independent product and process claims 1,

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20 and 32 are found allowable, then the dependent claims that define additional limitations to the allowed inventions should also be allowable. Pending composition claims 3-8 and 10-19 all depend ultimately from independent claim 1. Pending composition claims 34-37 all depend from independent claim 32. Pending method claims 21 and 24-31 all depend ultimately from amended independent claim 20. Hence, Applicants request reconsideration and allowance of all of the pending claims if amended claims 1, 20 and 32 are found allowable.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims, as amended, are patentable and in condition for allowance. Accordingly, withdrawal of the rejections and allowance of the application is earnestly solicited. The undersigned has made a good-faith effort to address all the points raised in this Office Action and to place the claims in condition for allowance. If minor matters remain, however, that could be resolved by a telephone interview, the Examiner is invited to contact the undersigned at the number below.

Fee Authorization

Applicants believe that no fee is due in connection with filing this amendment after final rejection, but if that is incorrect, then authorization is hereby provided to debit any fees associated with this filing from the USPTO deposit account number 07-0835 maintained by Gen-Probe Incorporated.

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being filed electronically, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Respectfully submitted,

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